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*Sun Pharmaceutical Industries Ltd.*  
*Sun Pharmaceutical Industries Inc.*  
*Caraco Pharmaceutical Laboratories, Ltd.*

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

THE MEDICINES COMPANY,

Plaintiff,

v.

SUN PHARMA GLOBAL FZE, SUN  
PHARMACEUTICAL INDUSTRIES LTD.,  
SUN PHARMACEUTICAL INDUSTRIES INC.,  
and CARACO PHARMACEUTICAL  
LABORATORIES, LTD.,

Defendants.

Civil Action No. 3:11-cv-06819  
(PGS)(DEA)

**ANSWER**

Defendants Sun Pharma Global FZE (“Sun FZE”), Sun Pharmaceutical Industries Ltd. (“Sun Ltd.”), Sun Pharmaceutical Industries Inc. (“Sun Inc.”), and Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) (collectively, “Sun”), by and through their undersigned attorneys, answer plaintiff The Medicines Company’s (“TMC”) complaint dated November 21, 2011 (“Complaint”) as follows:

**Nature of the Action**

1. Admitted that TMC purports to bring this action under the patent laws of the United States, Title 35, United States Code, for alleged infringement of the United States Patent Nos. 7,582,727 (“’727 patent”) and 7,598,343 (“’343 patent”). Otherwise denied.

**The Parties**

2. Sun states that it is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 2 and, therefore, denies those averments.

3. Admitted with the following clarification: Sun FZE is an entity organized and existing under the laws of Sharjah, United Arab Emirates.

4. Admitted.

5. Admitted that Sun FZE is a subsidiary of Sun Pharma Global Inc., which is a subsidiary of Sun Ltd. Otherwise denied.

6. Admitted that Sun Inc. is an entity organized and existing under the laws of the State of Michigan. Otherwise denied.

7. Admitted that Sun Inc. is registered to do business in New Jersey. Sun Inc. has its principal place of business at 270 Prospect Plains Rd., Cranbury, NJ 08512. Otherwise denied.

8. Admitted that Sun Inc. is a subsidiary of Sun Ltd. To the extent that Paragraph 8 of the Complaint implies that Sun Ltd. and/or Sun FZE conducts business through and with Sun Inc. related to the subject matter of the ’727 patent, the ’343 patent, or ANDA No. 203381 (“Sun FZE’s ANDA”), denied. Otherwise denied.

9. Admitted.

10. Admitted that Caraco is registered to do business in New Jersey.

Otherwise denied.

11. Admitted that Caraco is a directly- and indirectly-owned subsidiary of Sun Ltd. Otherwise denied.

12. Admitted that Caraco is a subsidiary of Sun Ltd. To the extent that Paragraph 12 of the Complaint implies that Sun Ltd. and/or Sun FZE conducts business through and with Caraco related to the subject matter of the '727 patent, the '343 patent, or Sun FZE's ANDA, denied. However, admitted that Caraco has distributed in the United States pharmaceutical products marketed by Sun Ltd., Sun FZE, and Sun Inc. Otherwise denied.

13. Sun incorporates its responses to Paragraphs 3-12 herein. Otherwise denied.

#### **Jurisdiction and Venue**

14. Admitted.

15. For purposes of this litigation only, Sun Ltd., Sun FZE, Sun Inc. and Caraco consent to the Court exercising personal jurisdiction over them. Otherwise denied.

16. For purposes of this litigation only, Sun does not contest that venue is proper in this district. Otherwise denied.

#### **Facts As to All Counts**

17. Admitted, on information and belief.

18. Admitted that the '727 patent is entitled "Pharmaceutical Formulations of Bivalirudin and Processes of Making the Same" and states on its face that it issued

September 1, 2009, that the inventors are Gopal Krishna and Gary Musso, and that the assignee is TMC. Otherwise denied.

19. Admitted that the '343 patent is entitled "Pharmaceutical Formulations of Bivalirudin and Processes of Making the Same" and states on its face that it issued October 6, 2009, that the inventors are Gopal Krishna and Gary Musso, and that the assignee is TMC. Otherwise denied.

20. Admitted that the '727 patent and the '343 patent are listed patents for Angiomax in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") published by the FDA. Otherwise denied.

21. Admitted that Sun FZE submitted to the FDA Abbreviated New Drug Application No. 203381 seeking approval to market Bivalirudin for Injection, 250 mg/vial, for the indications approved by the FDA ("Sun FZE's Bivalirudin") before the expiration of the '727 and '343 patents. Otherwise denied.

22. Admitted that Sun Ltd. has a DMF for the manufacturing, packaging, and control of bivalirudin on file at the FDA. Otherwise denied.

23. Admitted that on or about October 11, 2011, Sun FZE sent TMC a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) notifying TMC that Sun FZE's ANDA contains a Paragraph IV certification for the '727 patent and the '343 patent ("Paragraph IV Certification"). Otherwise denied.

24. Admitted that 21 U.S.C. § 355 and 21 C.F.R. § 314.95 set forth certain requirements concerning detailed statements, and that the statute and regulation contain the quoted language. Otherwise denied.

25. Denied.

**Count I**

26. Sun repeats and realleges its responses to each of the foregoing paragraphs as if fully set forth herein.

27. Admitted that Sun FZE seeks FDA approval to market Sun FZE's Bivalirudin. Otherwise denied.

28. Admitted that Sun FZE's ANDA includes a Paragraph IV Certification for the '727 patent and seeks approval to market Sun FZE's Bivalirudin before expiration of the '727 patent. Otherwise denied.

29. Admitted that Sun FZE intends to market Sun FZE's Bivalirudin in the United States after receiving final approval by the FDA. Otherwise denied.

30. Admitted that, as of the date of Sun FZE's Notice Letter for Sun FZE's ANDA, Sun FZE was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). Otherwise denied.

31. The filing of an ANDA with a Paragraph IV certification is a technical act of infringement under 35 U.S.C. § 271(e)(2) by the ANDA filer. Otherwise denied.

32. Denied.

33. Denied.

34. Admitted that Sun is aware of the existence of the '727 patent. Otherwise denied.

35. Denied.

**Count II**

36. Sun repeats and realleges its responses to each of the foregoing paragraphs as if fully set forth herein.

37. Admitted that Sun FZE seeks FDA approval to market Sun FZE's Bivalirudin. Otherwise denied.

38. Admitted that Sun FZE's ANDA includes a Paragraph IV Certification for the '343 patent and seeks approval to market Sun FZE's Bivalirudin before expiration of the '343 patent. Otherwise denied.

39. Admitted that Sun FZE intends to market Sun FZE's Bivalirudin in the United States after receiving final approval by the FDA. Otherwise denied.

40. Admitted that, as of the date of Sun FZE's Notice Letter for Sun FZE's ANDA, Sun FZE was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). Otherwise denied.

41. The filing of an ANDA with a Paragraph IV certification is a technical act of infringement under 35 U.S.C. § 271(e)(2) by the ANDA filer. Otherwise denied.

42. Denied.

43. Denied.

44. Admitted that Sun is aware of the existence of the '343 patent. Otherwise denied.

45. Denied.

#### **Affirmative Defenses**

46. For its further and separate defenses to the allegations of the Complaint, and without assuming any burden of proof it would otherwise not bear under applicable law, Sun pleads as follows:

#### **First Affirmative Defense**

47. TMC fails to state a claim on which relief can be granted.

**Second Affirmative Defense**

48. Sun has not infringed, does not infringe, and will not by the manufacture, use, sale, offer for sale, or importation of Sun FZE's Bivalirudin infringe, directly or indirectly, any valid and enforceable claim of the '727 patent.

**Third Affirmative Defense**

49. The claims of the '727 patent are invalid for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

**Fourth Affirmative Defense**

50. Sun has not infringed, does not infringe, and will not by the manufacture, use, sale, offer for sale, or importation of Sun FZE's Bivalirudin infringe, directly or indirectly, any valid and enforceable claim of the '343 patent.

**Fifth Affirmative Defense**

51. The claims of the '343 patent are invalid for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

**Sixth Affirmative Defense**

52. Any claim of infringement of the '727 patent or '343 patent would be limited by the doctrine of prosecution history estoppel.

**Seventh Affirmative Defense**

53. TMC fails to state a proper claim for willful infringement or exceptional case.

**Eighth Affirmative Defense**

54. The judgments that TMC seeks in paragraphs (c), (f), (i), and (j) of TMC's Prayer for Relief cannot be granted because the Court lacks subject matter jurisdiction. The relief requested in those paragraphs would be advisory in nature.

**Ninth Affirmative Defense**

55. The Complaint fails to state a cause of action under 35 U.S.C. § 271(e)(2)(A) against Sun Ltd., Sun Inc., and Caraco, because under § 271(e)(2)(A) the filing of an ANDA with a Paragraph IV certification is a technical act of infringement, and Sun Ltd., Sun Inc., and Caraco did not file Sun FZE's ANDA.

**Tenth Affirmative Defense**

56. The Complaint fails to state a cause of action under 35 U.S.C. §§ 271(a)-(c) against Sun because TMC has not plead with particularity facts regarding any post-ANDA-approval activities.



**Prayer for Relief**

WHEREFORE, Sun respectfully requests that the Court:

- A. dismiss with prejudice the entirety of TMC's Complaint;
- B. deny all remedies and relief sought by TMC;
- C. enter judgment in favor of Sun and against TMC on all claims;
- D. adjudge and declare that the claims of the '727 patent are invalid;
- E. adjudge and declare that Sun does not directly and/or indirectly infringe, and has not directly and/or indirectly infringed, any valid and enforceable claims of the '727 patent;
- F. adjudge and declare that Sun will not directly and/or indirectly infringe any valid and enforceable claim of the '727 patent by the commercial manufacture, use, sale or offer for sale in the United States, or importation into the United States, of Sun FZE's Bivalirudin;
- G. adjudge and declare that the claims of the '343 patent are invalid;
- H. adjudge and declare that Sun does not directly and/or indirectly infringe, and has not directly and/or indirectly infringed, any valid and enforceable claims of the '343 patent;
- I. adjudge and declare that Sun will not directly and/or indirectly infringe any valid and enforceable claim of the '343 patent by the commercial manufacture, use, sale or offer for sale in the United States, or importation into the United States, of Sun FZE's Bivalirudin;
- J. declare this to be an exceptional case under 35 U.S.C. § 285 and award Sun its attorneys' fees;
- K. award Sun its costs and expenses; and
- L. award Sun such other and further relief as the Court deems just and appropriate.

Respectfully submitted,

Dated: January 27, 2012

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*Caraco Pharmaceutical Laboratories, Ltd.*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories, Ltd., by their undersigned counsel, certify that the patents asserted by plaintiffs in this action are also the subject of the following actions:

- *The Medicines Company v. Dr. Reddy's Laboratories, Ltd., et al.*,  
Civil Action No. 11-CV-02456-PGS-DEA (D.N.J.)
- *The Medicines Company v. Sun Pharma Global FZE, et al.*,  
Civil Action No. 11-CV-15175 (E.D. Mich.)
- *The Medicines Company v. Hospira Inc.*,  
Civil Action No. 09-CV-00750 (D. Del.)
- *The Medicines Company v. Mylan Inc., et al.*,  
Civil Action No. 11-CV-01285 (N.D. Ill.)

Respectfully submitted,

Dated: January 27, 2012

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